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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,145	11/07/2005	Frank Mayer	DREISS-2	7018
23599 7590 09/16/2008 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER VOGEL, NANCY TREPTOW				
ART UNIT		PAPER NUMBER		
1636				
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09/16/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/520,145

**Applicant(s)**

MAYER ET AL.

**Examiner**

NANCY VOGEL

**Art Unit**

1636

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date 1/3/05, 7/19/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-24 are pending in the case.

Receipt of the Information Disclosure Statements on 1/3/05 and 7/19/06 is acknowledged. References on the Statement of 1/3/05 have been struck through since copies have not been received.

### ***Election/Restrictions***

.Applicant's election with traverse of Group I, claims 9-14, in the reply filed on 3/12/08 is acknowledged. The traversal is on the ground(s) that there is not burden for examination of all of the claims. This is not found persuasive because it is maintained that the search for both groups would not be the same, since they are drawn to different subject matter requiring different search and consideration, as was set forth in the election requirement. It is noted that claims 1-8 have been amended to be in correct form and are included in the instant examination.

The requirement is still deemed proper and is therefore made FINAL. Claims 15-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/12/08.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Sequence compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences are set forth in the specification and drawings that lack sequence identifiers. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 244.02). If the sequences are already present in the sequence listing, it would be remedial to amend the Brief Description of the Drawings to include the appropriate sequence identifiers. Applicants are required to comply with all of the requirements of 37 CFR 1.821 - 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F. R. 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

### ***Drawings***

The drawings are objected to because it is not clear whether some of the sheets of drawings are intended to be parts of particular Figures, since it is not clear how and whether some of the sheets are intended to belong to a numbered Figure. Furthermore

some of the text in the Drawings is in German. Furthermore, the Drawings to not appear in some cases to correspond to the descriptions in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: some of the descriptions of the Figures does not appear to correspond to the content in the Figures.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 23, 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, claims 1-8 are drawn to methods of cell digestion comprising employing a substance that binds to a component of the cytoskeleton, especially to EF-Tu, and therefore any cell is encompassed, and any substance which has the specified ability is encompassed, and any component of the cytoskeleton is encompassed (in claim 1, 2, 5, 6, 8). Claims 9-14 are drawn to methods for digestion of any cell comprising destabilizing a component of a cytoskeleton. The claims encompass any cell, any component of the cytoskeleton (9, 10, 13, 14.), any method of destabilizing a component of a cytoskeleton (claim 9 and possibly other claims), employing any substance that binds to the component of the

cytoskeleton (10, 14). While the specification has adequate written description of method for cell digestion of bacterial cells using the substance which is particular domains of the EF-Tu molecule, there is no disclosure on the structural limitations of the genus represented by any other cell types, and any other substances other than those domains of EF-Tu which bind to regions of EF-Tu and result in cell digestion. There is no structural information on which types of molecules, other than EF-Tu domains, would have the recited activity. One skilled in the art would conclude that the disclosure of the recited method of digestion of bacterial cells, using particular regions or domains of EF-Tu, that bind to particular areas of EF-Tu and result in cell digestion, is not representative of the undefined genus of cells and substances recited in the claims. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. .

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, and 11-14, 23, 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1-8 are vague and indefinite in the recitation in claim 1 of "a component of the cytoskeleton, especially to EF-Tu". A broad range or limitation together with a

narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "a substance that binds to a component of the cytoskeleton", and the claim also recites "especially to EF-Tu" which is the narrower statement of the range/limitation.

Claim 8 is vague and indefinite in the recitation of "The method according to claim 1 wherein the is a linear or cyclic peptide..." Text appears to be missing from the claim and therefore the intended subject matter cannot be determined.

Claims 5 and by dependence claim 6, are vague and indefinite in the recitation of "wherein the substances contain partial segments of the amino acid sequences from the domains 2 and/or 3 with a length of at least four amino acids". The claims are dependent on claim 1, in which a method for cell digestion comprising "employing a substance that binds to a component of the cytoskeleton, especially to EF-Tu" is recited.



Therefore, claim 1 does not recite that the "substance" that binds to a component of the cytoskeleton, especially to Ef-Tu, is any particular molecule, and therefore the recitation in claim 5 that the substances [sic] "contain partial segments of the amino acid sequences from the domains 2 and/or 3..." does not have a clear meaning.

Claim 4, 5, 7, are vague and indefinite in the recitation of "wherein the substances" since the claim on which these claims depend, i.e. claim 1, recites "a substance", not "substances".

Claims 3, 4, 12, 23, are vague and indefinite in the recitation of particular amino acid numbers in particular domains of EF-Tu, since it is not expected that the numbering of amino acids would be identical in EF-Tu molecules from all encompassed organisms. Therefore it is not clear what molecules are intended and the intended metes and bounds of the claims cannot be determined.

Claims 23 and 24 are vague and indefinite in the recitation of "wherein the substance binds to the EF-Tu in the area of..." (23) or "wherein the substance comprises a partial segment of the amino acid sequence from the domains..." (24). The claims are dependent on claim 9, which recites "A process for digestion of a cell comprising destabilizing a component of a cytoskeleton". There is no recitation of a "substance" or "EF-Tu" in claim 9. There is no recitation which clarifies what is intended by "the domains" in claim 24.

Claims 11, 12, 13, are vague and indefinite in recitation of "wherein the substance binds to ..." or "the substance comprises...." since the claim is dependent on claim 9 and there is no recitation in claim 9 of a "substance". Furthermore, claim 13

recites "a partial segment of the amino acid sequence from the domains 2 and/or 3..." without clarifying what molecule is be referred to, similarly to claim 5 (see above).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10, are rejected under 35 U.S.C. 102(b) as being anticipated by .Sauman et al. (Int. J. Dev. Biol. 37:441-450, 1993).

Sauman et al. disclose a method for cell digestion comprising employing a substance, cytochalasin-D, that binds to a component of the cytoskeleton, i.e. actin (page 447, right and left col). The cytochalasin-D destabilizes a component of the cytoskeleton by binding to a component of the cytoskeleton, since cytochalasin-D is known to bind to actin and to disrupt actin based structures (see page 444, left column). Cell death or apoptosis would involve "digestion" or lysis of the cell.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

NV  
9/12/08